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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,552

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Hubert Kurnsteiner

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06/22/2007

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

EXAMINER

WALICKA, MALGORZATA A

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

06/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,552	Applicant(s) KURNSTEINER ET AL.	
	Examiner Malgorzata A. Walicka	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 21 is/are allowed.
- 6) ☒ Claim(s) 2, 7, 16, 17 and 22 is/are rejected.
- 7) ☒ Claim(s) 1, 3-6, 8-15, 18-20 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>March 11, 2005</u> . | 6) <input type="checkbox"/> Other: ____. |

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The application is the national stage application of PCT/EP03/010289.

Preliminary amendment was filed together with the application. In the amendment claims 1, 2, 7, 8, 13 and 22 have been amended. Claims 1-22 are pending and under examination.

DETAILED ACTION

Priority

Applicants claim of the benefit of priority to the Austrian application 1297/202, filed 09/17/2002 has been noted. Since the priority documents have not been filed, the priority of the instant claims to the date of filing the Austrian application has not been granted.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

Objections

Claims 1 and 2 are objected to because they use the verb "codes for" which should be "encodes".

Claims 9-12 are objected to because they recite "coding for", which should be "encoding".

Claims 4-8 are objected to because they use the term "base" to mean "nucleotide". The sequences referred to in the claims are nucleotide sequences.

Rejections

35 USC 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7, 16 and 22 are rejected are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the transitional phrase "consisting essentially of" which is unclear absent the appropriate definition in the disclosure. For examination purposes "consisting essentially of" is treated as the open phrase "comprising"; see MPEP 2111.03.

Claim 16 is rejected because it is not clear whether a host cell is in the body of larger organism or it is an isolated host cell.

35 USC 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

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Claims 2, 7 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 7 and 22 are rejected as containing new matter. The disclosure as filed does not contain the phrase "consisting essentially of".

Claims 16-17 are rejected as generic and directed to a transformed host and the use of said transformed host for production of cephalosporin C, wherein the transformed host comprises a vector encoding a protein comprising SEQ ID NO: 1.

Applicants disclose protein of *Acremonium chrysogenum*, set forth by SEQ ID NO: 1, which when overexpressed in *A. chrysogenum* increases production of cephalosporin C; see page 6 of the specification, the last paragraph, and page 13 line 9. Also when *A. chrysogenum* is transformed with a plasmid further comprising genes *cefEF* and *cefG* of *A. chrysogenum*, some of the resulting transformants produce 10% more antibiotic than not transformed *A. chrysogenum* (page 18 Example 8). The disclosure misses any teaching as to other host cells, microorganisms or not, that after transformation with DNA encoding protein of SEQ ID NO: 1 produce cephalosporin C.

For that reasons, one having skills in the art is not convinced that applicants were in possession of the claimed invention at the time the application was filed.

Claims 18, 19, 20 are objected to as depending on the rejected claims 16 and 17.

Scope of enablement

Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of production cephalosporin C by A. chrysogenum transformed with a DNA molecules encoding protein of SEQ ID NO: 1, does not reasonably provide enablement for production of cephalosporin C by any host cell transformed with such DNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention.

Factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses the product that is a host cell transformed with DNA encoding protein of SEQ ID NO: 1 with intention of use of said product for production of cephalosporin C. Although biotechnological

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production of cephalosporin C is well developed, not any host cell is capable of producing cephalosporin. Only a host cell that produces enzymes necessary for all the steps of cephalosporin C synthesis may be used for production of this antibiotic after transformation with a DNA encoding protein of SEQ ID NO: 1. The protein of SEQ ID NO: 1 is not disclosed by applicants as involved in any step of biochemical synthesis of cephalosporin C, because it is tentatively identified as an acetyl-CoA hydrolase (page 6 of the specification). The biosynthesis of cephalosporin involves several steps, and if a host cell, by nature or by earlier engineering, does not produce the enzymes necessary for every step of the biosynthesis of cephalosporin C, introducing a DNA encoding SEQ ID NO: 1 will not cause production of that antibiotic. The filamentous fungus *Acremonium chrysogenum* is the industrially most important producer of cephalosporin C. Applicants have not provided working examples, and sufficient guidance regarding the feature of other host cells, so as to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims.

In conclusion, without a specific guidance as to what host is to be used for transformation and production of cephalosporin C, the experimentation left to a skilled artisan has a low probability of success and is undue.

CONCLUSION

Claims 2, 7, 16, 17 and 22 are rejected. Claims 1 and their dependent claims

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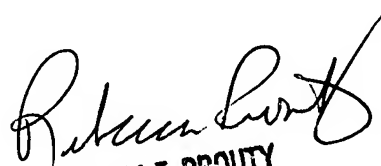
are objected to because claim 1 is objected to for grammatical error. Claims 18-20 are objected to as depending on the rejected claims 16 and 17. Claim 21 is allowed. The following is the examiner's reasons for indicating allowable subject matter. Applicants disclosed polypeptide of SEQ ID NO: 1 from *Acremonium chrysogenum*, which when overexpressed in *A. chrysogenum* increases production of cephalosporin C. Applicants also disclosed genomic and cDNA molecules encoding SEQ ID NO: 1. No prior art teaches or suggest the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

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Patent Examiner


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